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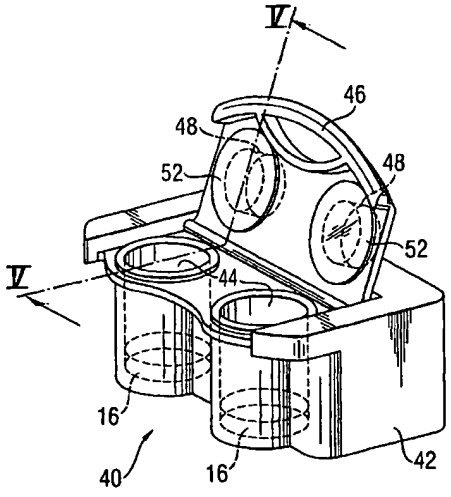
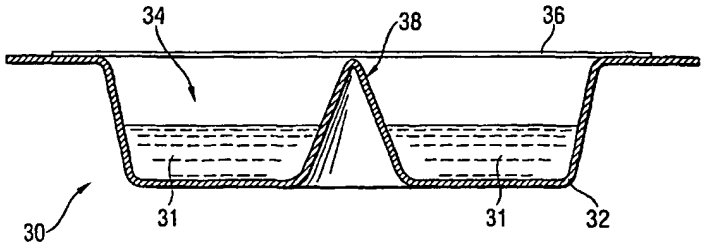
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STORAGE DEVICES AND ASSOCIATED APPARATUS





(57) Abstract: One embodiment of the invention relates to a storage device for fluids, the device comprising means defining a storage cavity; a cover for said cavity, and piercing means integral with said cavity defining means for piercing said cover. Another embodiment of the invention relates to testing apparatus comprising one or more reactionchambers, means for sealing said reaction chambers, and means for dispensing a predeterminedamount of fluid into said reaction chambers.

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STORAGE DEVICES AND ASSOCIATED APPARATUS

Technical Field

This invention relates, in one embodiment, to storage devices and, in another embodiment, to associated apparatus - for example to testing apparatus including such storage devices.

Prior Art:

It has previously been proposed to package pharmaceuticals, such as aspirin or paracetamol tablets for example, in so-called "blister packs". The underside of one such previously proposed blister pack is shown in Figure 1.

As shown, the pack comprises a plastic substrate 1 in which a plurality of storage cavities 3 has been formed. The storage cavities, and typically the whole of the substrate, are covered with a piercable foil cover (not visible).Within each of the cavities there is provided a solid tablet (not visible).The plastics substrate 1 is typically thin enough, or of such suitable material - at least in the region of each cavity, to enable it to be deformed towards the cover to drive the tablet in a given cavity towards the cover to pierce the same so that the tablet may be removed from the pack for use.

In this previously proposed arrangement, the tablet acts as a tool for piercing the cover, and these previously proposed blister packs have become very popular for the supply and storage of pharmaceuticals.

However, as the tablet is used to pierce the cover in these previously proposed devices, they are typically unsuitable for the supply or storage of fluids, such as liquids or powder, as deforming a fluid filled cavity towards it cannot easily pierce the cover.

One might think that a simple solution to this problem would be to pierce the cover from the outside (i.e. from the side opposite to the cavities) however this is not preferred as it is can then be difficult to remove all of the contents from the cavity. This is a particular disadvantage in applications where the cavity typically includes a specific dosage.

Another previously proposed storage device, particularly for fluids, comprises a cavity formed in a plastics body over which a cover is provided. Such storage devices have been used for a variety of different purposes, and one common use is for the storage of small quantities of milk that can be removed from the storage device to whiten tea or coffee, for example. To remove the milk or other fluid from the storage device, the user must first peal the cover from the body by pulling on a portion of the cover to break the seal between the cover and the body.

Unfortunately, due to the substantial force that must be applied to the cover to remove it from the body it is common for some of the liquid, in this case milk, to spill from the body when the device is opened. Whilst this is not a serious problem when the device is used for the storage of milk, it is a serious problem when the device is used for the storage of chemical solutions as it is no longer possible to determine the exact dosage of chemical solutions in the device since an unknown quantity has been spilt therefrom and the chemical solution may be harmful.

Some problems concerning the removal of solid contents from blister packs have been alleviated by DE 4400083 A1, which describes a blister pack for finely dispersed solid contents, which blister pack comprises a container foil comprising at least one cavity and a cover foil. The described elements make it possible to easily remove solid contents to a large amount from a blister pack without impairing the finely dispersed form of the solid contents.

Description of Invention

It is an object of an embodiment of the invention to alleviate at least some of these problems. In pursuance of this object, a first embodiment of the invention provides a storage device for fluids, the device comprising means defining a storage cavity; a cover for said cavity, and piercing means integral with said cavity defining means for piercing said cover. This embodiment of the invention alleviates the above described problems as the contents of the storage device are no longer responsible for piercing the cover - that being undertaken by the piercing means - with the effect that the storage device is now suitable for the storage of fluid (although it will be appreciated that the device may still be used for the storage of solids if desired).

As mentioned above, one advantage of a particular preferred aspect of this first embodiment is that it reduces the likelihood of fluid stored in the device becoming trapped in the cavity when the cover is pierced as the cover is pushed away from the device. In other words, one can be confident that when the cover is pierced substantially all of the fluid, for example, within the device may then be removed. Because of this, the storage device according to the first embodiment of this invention also finds utility in the field of testing apparatus.

In accordance with a further embodiment of the invention, there is provided a storage device for fluids, the device comprising means defining a storage cavity; a cover for said cavity, and piercing means external to said cavity defining means and operable to drive the cavity defining means to reduce the volume of the cavity and to cause the cover to be pierced from within the cavity. This embodiment of the invention avoids the spillage problems identified above whilst still allowing fluid to flow from the device once the cover has been pierced.

One previously proposed testing apparatus is shown in Figure 3. As shown, the testing apparatus comprises a plastics body 10 in which a pair of reaction chambers 12 are formed. The chambers 12

are closable with a lid 14, and have provided therein freeze-dried reagents 16. This previously proposed testing apparatus further comprises a dropper bottle 18 for solvent such as buffer solution, for example.

In one illustrative example, the testing apparatus is operable to test for the presence of *Helicobacter pylori* and the freeze-dried reagents include urea. To conduct this illustrative test, a biopsy is taken from the patient's gut and placed in the reaction chambers. Buffer solution is added from the dropper bottle to reconstitute the freeze-dried reagents, and the test is left for half an hour or so to allow the reaction to take place. If the patient has *Helicobacter pylori* in their gut, then the reaction mixture will turn pink and if *Helicobacter pylori* are not present then the reaction mixture will remain a yellow/orange colour. Whilst this previously proposed testing apparatus has previously been operated with great success, various problems have been encountered.

A first problem associated with this apparatus is concerned with the fact that the reaction time (i.e. the time required for the reagents to indicate whether or not the patient sample contains *Helicobacter pylori*) is heavily dependent upon the amount of solvent placed in the reaction chambers. With a few drops of solvent, the reaction time should be in the region of thirty minutes, however with more solvent the reaction time can increase to several hours. This is undesirable for a "while you wait" test.

Another problem is concerned with the fact that these previously proposed testing apparatus are not particularly environmentally friendly. All the tests are disposable, and this means that after a patient has been tested both the dropper bottle and plastics body are thrown away.

It would therefore be advantageous to provide a testing apparatus which allowed a predetermined amount of solvent or fluid reagent to be inserted into the reaction chamber, and/or which decreased the amount of material that must be thrown away once the test has been completed.

In accordance with a further embodiment of the invention, there is provided testing apparatus comprising one or more reaction chambers, means for sealing said reaction chambers, and means for dispensing a predetermined amount of fluid into said one or more reaction chambers.

This aspect of the invention alleviates the above mentioned reaction time problems by enabling a predetermined amount of fluid (which may be a solvent, a liquid reagent or a powder) to be dispensed into the reaction chambers.

Preferably, the dispensing means comprises an integral component of said testing apparatus. More preferably, the dispensing means comprises an integral component of said sealing means. These preferred aspects of the second embodiment reduce the environmental impact of the testing apparatus by reducing the amount of material required to manufacture the apparatus, and hence the amount of material that is thrown away after use.

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic representation of the underside of a previously proposed blister pack;
Figure 2 is a cross-sectional view of a storage device according to a first embodiment of the invention;
Figure 3 is a schematic representation of a previously proposed testing apparatus;
Figure 4 is a schematic representation of a testing apparatus according to a second embodiment of the invention that includes storage devices similar to those shown in Figure 2;
Figure 5 is a cross-sectional view along the line IV-- IV of Figure 4.

As mentioned above, Figure 1 shows a previously proposed blister pack, which comprises a plastics substrate 1 in which a plurality of storage cavities 3 have been formed. The storage cavities, and typically the whole of the substrate, are covered with a piercable foil cover. Within each of the cavities there is provided a solid tablet. The plastics substrate 1 is typically thin enough, or of such suitable material (at least in the region of each cavity) to enable it to be deformed towards the cover. Deforming the substrate in this way drives the tablet in a given cavity towards the cover 5 to pierce the same so that the tablet may be removed from the pack for use. Whilst these blister packs are useful for the supply of tablets, they are unsuitable for the storage of fluids as the cover cannot easily be pierced by deforming a fluid filled cavity towards it.

Figure 2 is a schematic representation of a storage device 30 according to a first embodiment of the invention that is suitable for the storage of fluids (although it will be appreciated that it could also be used for the storage of solids). The fluid may be a solvent, a reagent or a solute (in liquid or powder form). In Figure 2, the illustrative storage device is shown storing a liquid 31 that may be a chemical reagent or a solvent, or both or a fluid, milk for example.

Whilst Figure 2 shows a single storage device, it will be appreciated that blister packs similar to those of Figure 1 may be formed that comprise a plurality of storage devices such as those shown in Figure 2.

The storage device 30 comprises a support material 32 (preferably of plastics material with low moisture vapour transmission rate) in which a cavity 34 has been formed. The cavity 34 contains a predetermined quantity of fluid 31 and is covered with a cover 36 that is preferably of foil or similar material so that it may easily be pierced and also have low moisture vapour transmission rate to give stability to the contents of the storage device over the storage lifetime. The substrate 32 is typically thin enough, or of such suitable material - at least in the region of the cavity 34, to enable it to be deformed towards the cover 36.

Within the cavity 34 there is provided piercing means 38 that in this embodiment comprises a spike. Whilst it is preferred for manufacturing simplicity that the piercing means comprises a spike, it will be appreciated that many alternative arrangements may instead be provided. The piercing means is

formed as an integral component of the substrate, and preferably as an integral component of the portion of the substrate that defines the cavity.

The substrate 32 in the region of the cavity may be deformed, by squeezing for example, towards the cover to drive the piercing means (i.e. the spike) to pierce the cover. Once the cover has been pierced fluid, for example, within the storage device may then be dispensed therefrom. Advantageously, by piercing the cover from inside the cavity the likelihood of fluid being trapped within the storage device is reduced as fractured cover portions will be driven away from the support material, and thus there will be less chance that they will interfere with fluid flow from the storage device.

In a further embodiment of the invention not illustrated in the drawings, the means for piercing the cavity may be external to the device and operable to drive the substrate towards the cover so that the pressure in the cavity is increased to the point at which the cover bursts. Alternatively, the external piercing means may simply pierce the substrate and cover without relying on an increase in pressure to cause cover fracture. This embodiment of the invention alleviates the spillage problems associated with pulling the cover from the substrate, and also avoids the problems associated with fluid being retained in the device once the cover has been pierced. The piercing means may simply comprise a spike.

Figure 3 is a schematic representation of a previously proposed testing apparatus. As shown, the testing apparatus comprises a plastics body 10 in which a pair of reaction chambers 12 are formed. The chambers 12 are closable with a lid 14, and have provided therein freeze-dried reagents 16. This previously proposed testing apparatus further comprises a dropper bottle 18 for solvent such as buffer solution, for example. The plastics body is extended so that the bottle 18 may be stored in the region 19 of the body shown in ghost.

To use this previously proposed testing device, samples of tissue from a patient's body are placed in the reaction chambers and the freeze-dried reagents are then reconstituted by the addition of drops of buffer from the dropper bottle 18. The lid 14 is then closed and the apparatus is left until the test is completed.

Figure 4 is a schematic representation of a testing apparatus 40 according to a second embodiment of the invention that includes storage devices similar to those shown in Figure 2; and Figure 5 is a cross-sectional view along the line V- -V of Figure 4.

The testing apparatus 40 comprises a main body 42 in which a pair of reaction chambers 44 have been formed. The reaction chambers 44 can be sealed by a lid 46, which is pivotally attached to the main body 42. In this embodiment, the lid has a pair of storage devices 48 integrally formed therewith, one for each of the two reaction chambers 44. The storage devices 48 are similar to those shown in Figure 2 and each comprise a cavity 50, which is covered by a cover 52 (preferably of foil). The base of each of the cavities include piercing means 54 (which in this embodiment are a spike) that are driveable towards the cover to pierce the same, and thereby to release the fluid stored within.

The apparatus of Figure 4, in this illustrative example, is suitable for use as a "while you wait" test for *Helicobacter pylori*. It will be appreciated, however, that the testing apparatus may be used for a variety of different diagnostic tests. In this illustrative example, the storage devices store buffer solution as a solvent, and the reaction chambers each include a freeze-dried reagent 16 that includes urea.

To use the apparatus for a "while you wait" test for *Helicobacter pylori*, patient samples (in this case biopsies from the patient's gut) are inserted in each of the reaction chambers, and then the lid is closed to seal the chambers. The storage devices are then operated by pressing on the wall of each cavity to drive the spikes towards their respective covers. Once the spikes have pierced the covers, the fluid within the storage devices is then free to run into the reaction chambers to reconstitute the freeze-dried reagents so that the test can take place. If the patient does have *Helicobacter pylori* in their gut, then the reaction mixture will turn pink. On the other hand, if the patient does not have *Helicobacter pylori*, then the reaction mixture will remain yellow/orange.

It is apparent therefore that the second embodiment of the invention avoids problems associated with increased reaction times, as only a predetermined quantity of fluid is dispensed into the reaction chambers and is therefore simpler to use. In addition, as the size of the testing apparatus is greatly reduced in comparison to that of Figure 3 the apparatus of the second embodiment is more environmentally friendly than previously proposed devices.

In a further embodiment of the invention not illustrated in the drawings, the cover of the said storage device may have attached to the outside an absorbent pad, such as glass fibre or paper. Once the foil is pierced the fluid is absorbed into the absorbent pad which can be used for controlling the rate of fluid delivery for example if the storage device was coupled to a lateral flow immunoassay test strip or flow through immunoassay device.

As mentioned above, the storage device described herein may be used with the diagnostic testing apparatus, and in particular as a storage device for wash and/or reagent solution.

It will also be understood that modifications may be made within the scope of the invention. For example, whilst the storage devices of one embodiment have been described as being integral components of the lid, it will be apparent that this need not be the case. The lid could simply comprise one or more holes through which a respective storage device (such as that shown in Figure 2) could be fitted. In addition, whilst the apparatus of the second embodiment is shown as having two reaction chambers, it should be noted that a greater or fewer number of chambers may instead be provided if desired. It will be apparent to persons skilled in the art that the storage device may be employed in a variety of different tests. Accordingly, the present description should not be read as being limited to any one particular test.

Claims

1. A storage device for fluids, the device comprising means defining a storage cavity; a cover for said cavity, and piercing means integral with said cavity defining means for piercing said cover.

2. A device according to Claim 1, wherein the piercing means is movable to pierce the cover.

3. A device according to Claim 1 or Claim 2, wherein movement of the cavity defining means towards the cover causes the piercing means to move to pierce the cover.

4. A device according to any preceding claim, wherein said cavity defining means comprises a plastics substrate.

5. A device according to any preceding claim, wherein said piercing means comprises a spike provided within the cavity.

6. A device according to Claim 4 and 5, wherein said spike extends from said plastics substrate towards said cover.

7. A storage device for fluids, the device comprising means defining a storage cavity; a cover for said cavity, and piercing means external to said cavity defining means and operable to drive the cavity defining means to reduce the volume of the cavity and to cause the cover to be pierced.

8. Testing apparatus comprising one or more reaction chambers, means for sealing said reaction chambers, and means for dispensing a predetermined amount of fluid into said reaction chambers.

9. Apparatus according to Claim 8, wherein the dispensing means comprises an integral component of said testing apparatus.

10. Apparatus according to Claim 8 or 9, wherein the dispensing means comprises an integral component of said sealing means.

11. Apparatus according to any of Claims 8 to 10, wherein the dispensing means comprises a storage device according to any of Claims 1 to 7.

12. Apparatus according to any of Claims 8 to 10, wherein the one or more reaction chambers are formed in a main body.

13. Apparatus according to Claim 12, wherein the sealing means comprises a lid hingedly mounted on said main body.

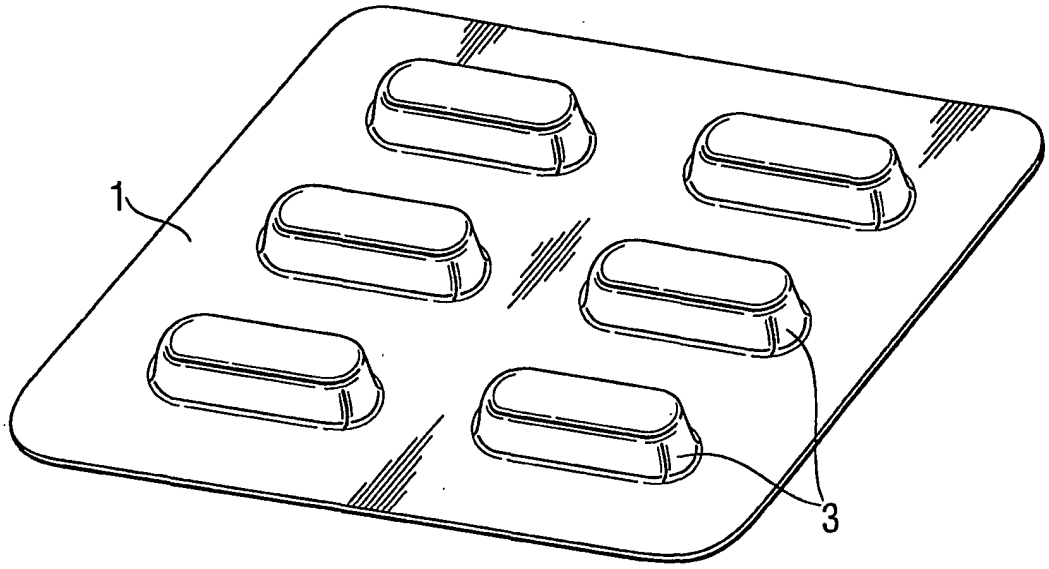
14. Use of a device according to any of Claims 1 to 7 for the storage of fluid.

15. Use of a device according to any of Claims 1 to 7 in a testing apparatus according to any of Claims 8 to 13.

16. A storage device substantially as hereinbefore described with reference to Figures 2 and 5 of the accompanying drawings.

17. Testing apparatus substantially as hereinbefore described with reference to Figure 4 of the accompanying drawings.

Fig. 1



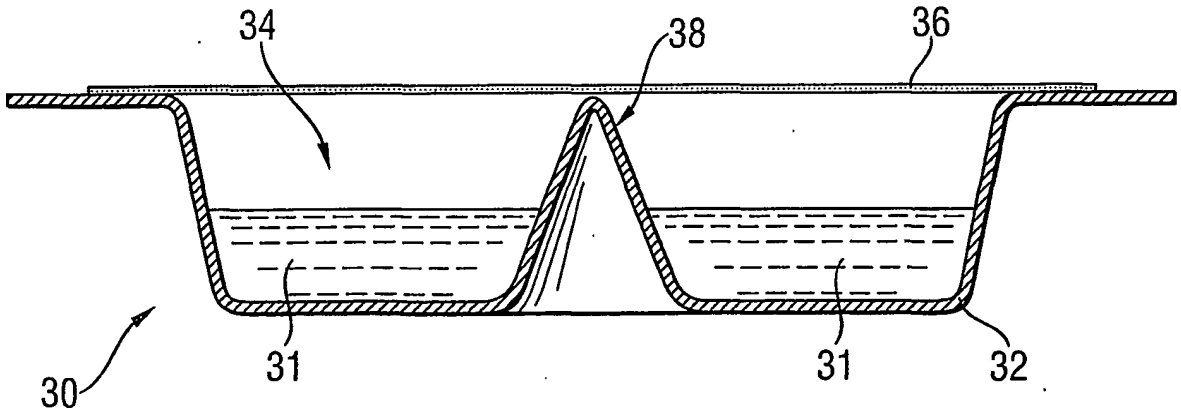


Fig. 2

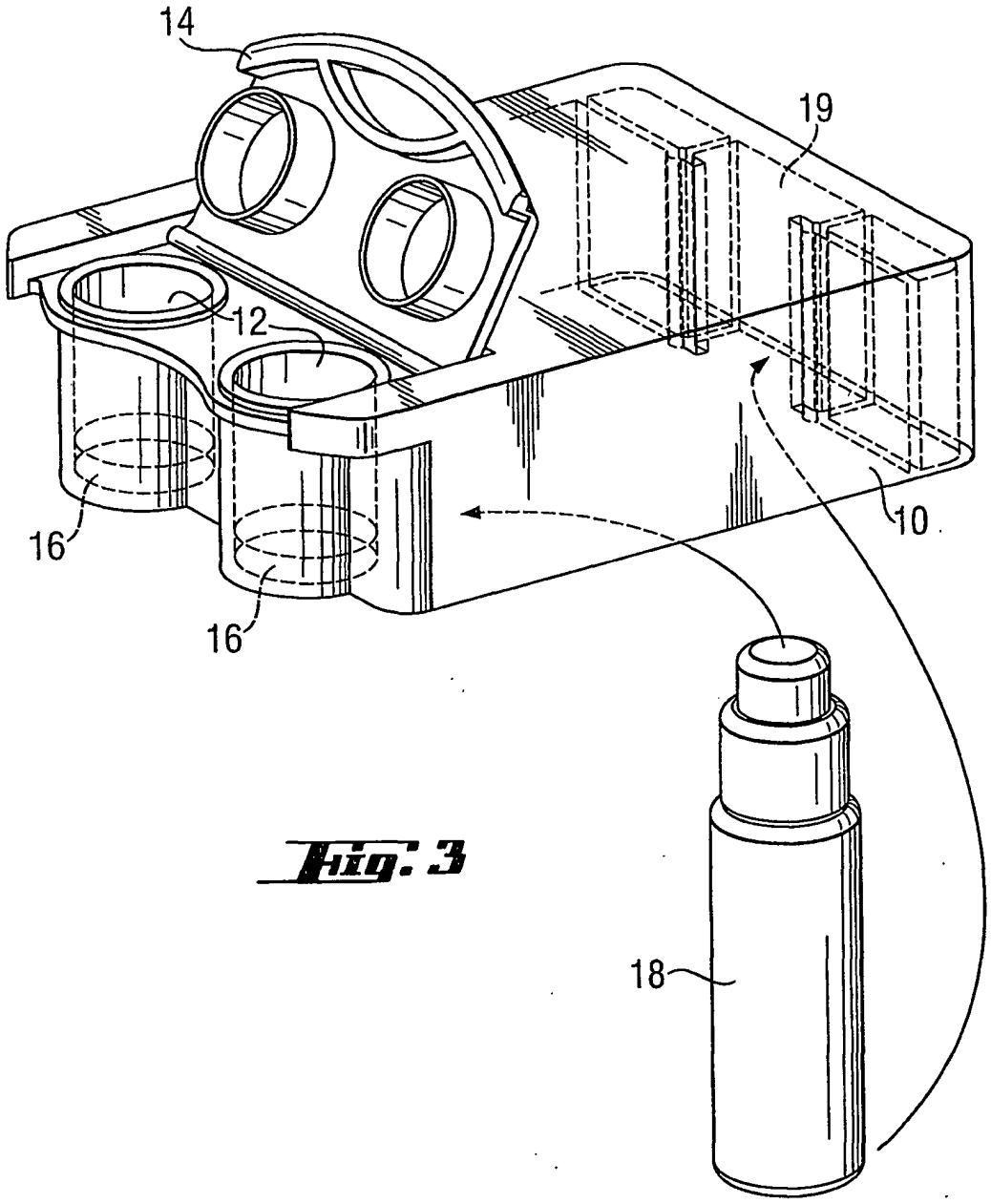


Fig. 3

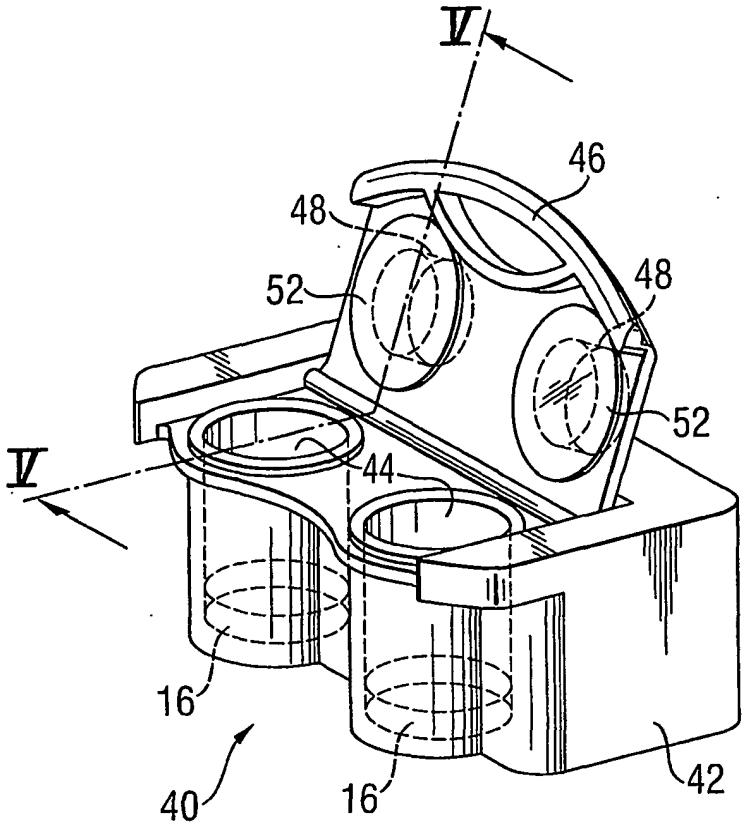


Fig. 4

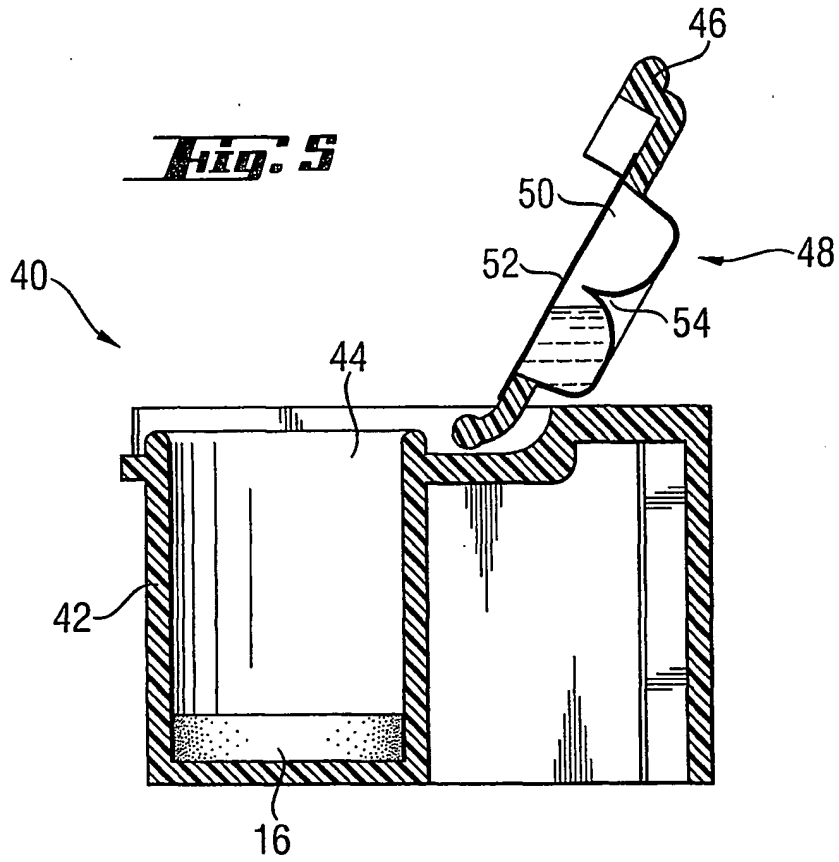


Fig. 5

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(74) Agent: **RUPP, Herbert**; c/o Byk Gulden Lomberg, Chemische Fabrik GmbH, P.O.Box 100310, 78403 Konstanz (DE).

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(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

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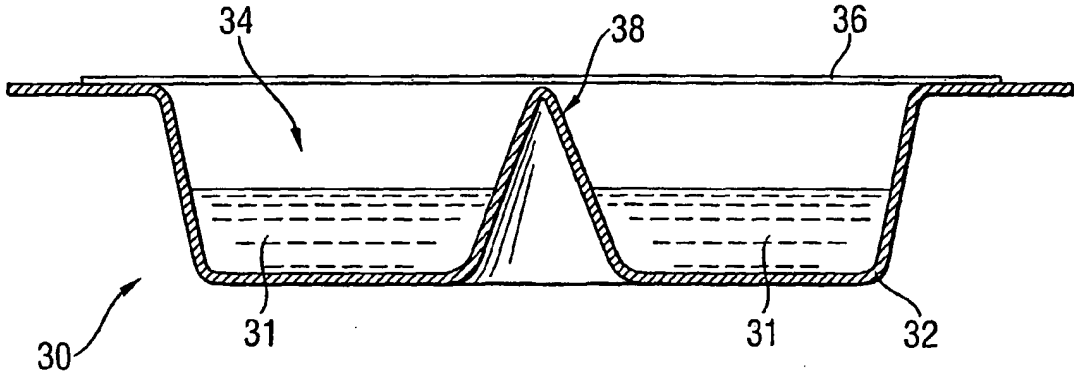

(57) Abstract: One embodiment of the invention relates to a storage device for fluids (31), the device comprising means defining a storage cavity (34); a cover (36) for said cavity, and piercing means (38) integral with said cavity defining means for piercing said cover. Another embodiment of the invention relates to testing apparatus comprising one or more reaction chambers (12), means for sealing (14) said reaction chambers, and means for dispensing (18) a predetermined amount of fluid into said reaction chambers.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B65D75/34 B65D75/58 B01L3/00 B01L3/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 B01L B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 72 03 746 U (FRITZ, ALFONS) 27 April 1972 (1972-04-27) page 1 -page 4; figures 1,5,6	1-6,14
X	US 4 136 202 A (FAVRE ERIC) 23 January 1979 (1979-01-23) figure 2	7
X Y	DE 25 33 052 A (BEHRINGWERKE AG) 27 January 1977 (1977-01-27) page 1, paragraph 1 -page 3, paragraph 3; figure 1	8-10,12 11,13,15
X	WO 97 48492 A (BACKMAN HENRY ;KAHMA KAUKO (FI); HELLMAN TAPANI (FI); KAPLAS ANTTI) 24 December 1997 (1997-12-24) page 1, line 3 -page 3, line 3; figures 4-7	8-10,12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2002	12 07 2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kamerbeek, M

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Intern I Application No
PCT/EP 01/08723

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 03265 A (OKAUCHI KANJI ;KYORITSU CHEMICAL CHECK LAB CO (JP)) 29 January 1998 (1998-01-29) abstract; figure 1	8-10,12
Y	US 5 255 812 A (HSU YU T) 26 October 1993 (1993-10-26) column 1, line 23 - line 29; figures 4,5 column 2, line 17 - line 22	11,15
Y	EP 0 290 019 A (ABBOTT LAB) 9 November 1988 (1988-11-09)	13
A	column 2, line 3 - line 47; figures 1,2	12
A	US 3 715 189 A (NIGHOHOSSIAN S ET AL) 6 February 1973 (1973-02-06) column 2, line 52 - line 58; figure 2B column 3, line 35 - line 42 column 5, line 30 - line 42	11
A	WO 97 25925 A (HULIOT PLASTICS IND ;QUALITY 9000 LTD (IL); INBAR MICHAEL (IL)) 24 July 1997 (1997-07-24) figure 2	12,13
A	FR 2 245 947 A (ERBA CARLO SPA) 25 April 1975 (1975-04-25) page 2, line 7 - line 9; figure 2	
A	US 4 785 931 A (WEIR DIXIE L ET AL) 22 November 1988 (1988-11-22) column 2, line 25 - line 31; figures 1-3	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-7,14

   Storage device for fluids with piercing means.

2. Claims: 8-13,15

   Testing apparatus

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 16,17

Claims 16 and 17 do not comply with rule 6.2(a) PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 01/08723

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 16,17
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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Internal Application No
PCT/EP 01/08723

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